

A critical evaluation of the quality management system at the medical company in the North West

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ABSTRACT

Quality management is the single most important process in any organization, whether for profit, nonprofit or an organization such as a health-care maintenance organization. It defines the purpose of quality for the organization it represents. Quality management is often forgotten, but it guarantees the quality in output from any organization and exists as an asset that always adds value to it. Quality Management System describes a situation where all business functions are involved in a process of continuous quality improvement. The International Organization for Standardization (ISO 9001:2008) is one of the quality systems commonly used by most organizations to provide businesses with the capability for their processes and requirements, or to give guidance on good management practice. This implies that the development and implementation of Quality Management Systems in government departments and the public sector will improve the quality of services delivery.

This study concerns the perceptions of the effect of the Quality Management System intervention that was implemented at one of the medical companies in the North West. The study is about the employee perceptions of the effect of the Quality Management System intervention that was implemented at one of medical companies in the North West. The findings of this study indicated that a Quality Management Systems are functioning in all the departments. The quality management system can be used to improve the level of service delivery in the company. A literature study was conducted to explore the QMS perceptions, QMS effectiveness, leadership, and employee satisfaction and employee morale of all the departments in the company. And finally, for the Quality Management System to be developed, implemented and maintained successfully. The introduction of ISO 9001:2008 is recommended.

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CHAPTER ONE

QUALITY MANAGEMENT

1.1 INTRODUCTION

Quality management is critical for all organizations and involves identifying and satisfying the needs of customers who demand high quality products and services, which are the organization's duty to offer. The International Organization for Standardization (ISO 9001:2008) is one of the quality systems commonly used by most organizations to provide businesses with the capability for their processes and requirements, or to give guidance on good management practice. ISO 9001:2008 was adopted as a tool in a grand strategy for achieving competitive advantage and providing a steppingstone on the way to Total Quality Management (TQM) practices. However, despite the benefits there were many barriers faced by organizations. ISO 9001 applies to all types of organizations, irrespective of size or what they do. It can help both product and service oriented organizations achieve standards of quality that are recognized and respected around the world. It might therefore be concluded that ISO 9001 complements rather than substitutes TQM.

The ISO was founded in Geneva in 1947, the original purpose of which was to provide standardization of technical specifications for products traded in the international marketplace. The term "ISO" derives from the Greek "isos," meaning "equal," and it has over 150 countries with more than 10,000 ISO standards used worldwide. These standards determine how various products and services are produced, and include those for film speed, thickness of credit cards, compact disc format, and screw thread number. Standardization has served an important role in promoting quality and compatibility of products on a global basis. The work of standardization is performed by ISO technical committees comprising representatives from interested member countries to address specific standards. Over the years the concept of standardization has evolved from specific technical specifications to a broader concept of generic quality management system standards. The concept was first brought to the United States of America (USA) by

the automobile industry in the late 1980s, because of a need to qualify the thousands of suppliers used by manufacturers. This effort was a concrete example of competitors working together to develop a quality framework that would serve them and their customers. The ISO 9001 family of quality management system standards was first developed in 1987 and revised in 1994 and 2000. The automobile industry described the specific standards for its suppliers in the QS 9000 system, and other industries have done the same with customized quality management system standards for the particular industry. For instance, in 2001, a set of preliminary standards for healthcare was published by the American Society for Quality in partnership with the Automotive Industry Action Group.

Today, more than 500,000 companies are ISO certified internationally, with approximately 38,000 in the USA. Worldwide, 65 percent of certifications are in manufacturing, with 90 percent in the USA in manufacturing. Approximately 100 healthcare entities in North America are certified, including 12 hospitals and 10 medical groups in the USA. There are many reasons for a healthcare facility to obtain ISO certification (ISO 9000 is the family of standards; an entity is certified to ISO 9001:2000). Establishing an ISO 9001 quality management system:

- provides for work performance consistency
- enables the discovery of causes of poor performance
- stresses the process approach
- defines goals and objectives for quality
- provides benchmarks by which to measure improvements

James (2011) argues that quality management requires customer focus and continual improvement. It provides for accountability within the system and ensures that the most important functions are carried out, while establishing a clear document system throughout the organization, a common language across the organization, and common identifiers for customers or patients.

1.2 BACKGROUND TO THE STUDY

James (2011) writes that in order to assist organizations to have a full understanding of the new ISO 9001:2008 it may be useful to have an insight on the revision process, how this reflects the inputs received from users of the standard, and the consideration given to benefits and impacts during its development. A tool for assessing the impacts versus benefits for proposed changes was created to assist the drafters of the amendment in deciding which changes should be included, and to assist in the verification of drafts against the identified user needs. The following decision-making principles were applied:

1. No changes with high impact would be incorporated into the standard
2. Changes with medium impact would only be incorporated when they provided a correspondingly medium or high benefit to users of the standard
3. Even where a change had a low impact, it had to be justified by the benefits it delivered to users, before being incorporated.

The changes incorporated in this ISO 9001:2008 edition were classified in terms of impact into the following categories:

- No changes or minimum changes on user documents, including records
- No changes or minimum changes to existing processes of the organization
- No additional training required or minimal training required
- No effects on current certifications.

The benefits identified for the ISO 9001:2008 edition fall into the following categories:

- Provides clarity
- Maintains consistency with ISO 9000 family of standards
- Improves translatability.

ISO 9001:2008 is implemented to improve business performance and obtain measurable financial results.

1.3 PROBLEM STATEMENT

Against the above background, the research question for this study is posed as follows: How does the company measure and monitor their product and services effectiveness? The company does not have a quality system; hence there is a gap, which ISO 9001:2008 will help the company to fill.

1.4 INVESTIGATIVE SUB-QUESTIONS

The investigative questions to be researched in support of the research question are as follows:

- Does top management understand the extent to which policies and procedures are required to change in order to comply with the requirements of the Quality Management System (QMS)?
- Is top management aware of the extent to which they may need to improve on the current infrastructure to establish process conformance to the QMS, and therefore customer requirements?
- To what extent should employees take ownership of the system to facilitate implementation of the required changes?
- To what extent are employee tasks required to be changed or revised in order to establish proof of process and product conformity to customer requirements?

The Company can use ISO 9001:2008 as a quality system because it:

- helps the company identify strengths and weaknesses
- aids the evaluation of organization
- establishes a basis for continuous improvement
- allows and supports external recognition
- increases customer focus

- improves continuous improvement (Oakland, 2003: 22).

It is clear that there would be a great advantage to this company having a quality system in place.

1.5 OBJECTIVES OF THE STUDY

This research seeks to evaluate an implemented QMS at one of the medical companies in the North West, focusing on employee perceptions of the effect of the QMS intervention. In South Africa, QMS implementation is common in the private sector, and it is critical for a QMS to be implemented in an organization. This research will therefore evaluate how this particular QMS will be developed, implemented and maintained.

As indicated by Madu and Kuei (1995), QMS describes a situation in which all business functions or services are involved in a process of continuous quality improvement, meaning that development and implementation of QMSs in the government departments and public sector will improve the quality of services delivery.

The primary objectives of the study are to:

- assess the challenges of organization when implementing a QMS
- establish the need for change management when implementing a QMS
- make recommendations to mitigate the research problem
- implement a vigorous processes to systematically eliminate defects and inefficiency
- deliver high performance, value and reliability to the customer. It is regarded and used around the world as one of the major themes for TQM .

The secondary objectives are to:

- understand the purpose of a QMS.
- know what to document and how to document it
- learn how to implement ISO 9001 in an effective and efficient manner.

1.6 SCOPE OF THE STUDY

That ISO 9001:2008 fulfils the requirements for QMS is now firmly established as the globally implemented standard for providing assurance of the ability to satisfy quality requirements and to enhance customer satisfaction in supplier-customer relationships.

1.7 RESEARCH METHODOLOGY

In this study, two techniques will be applied in the execution of the research. In phase 1 a literature review will be conducted while in phase 2 an empirical study will be carried out. A survey research methodology will be used for the study, and a questionnaire developed for this purpose because it offers the most cost effective method for securing feedback on the impact of ISO 9001 as a quality system in an organization.

1.8 LIMITATIONS OF THE STUDY

The following are limitations of the study:

- Time and Budget

There have been time and budget constraints.

- Population

The sample size of the organization has led to less generalized results.

- Access

The study depended on having access to people, organizations, or documents and, for whatever reason, access was denied or otherwise limited.

- Longitudinal effects

In studying a single research problem, the time to investigate it and to measure change or stability within the sample was constrained by the due date.

1.8 LAYOUT OF THE STUDY

Chapter 1 has introduced the mini-dissertation, with discussion devoted to issues such as problem statement, objectives of the study, research methodology and limitations of the study.

Chapter 2 contains a literature study on particular aspects of ISO 9001, including competitive advantages, the methodology, benefits and barriers.

Chapter 3 presents an exploratory empirical study with specific findings on research conducted on the evaluation of a quality management system in a specific medical company in the North West.

Chapter 4 presents a roadmap that includes strategic implementation, the process of implementation, organizational effectiveness model and the influence of quality in reliability and performance of the QMS.

Chapter 5 draws conclusions and makes recommendations regarding the successful implementation of ISO 9001.

CHAPTER 2

LITERATURE REVIEW: ISO 2001:2008 FUNDAMENTALS

2.1 INTRODUCTION

According to Spencer (2011), ISO 9001: 2008 is part of the ISO 9000 family of standards and is the document that lists the requirements an organization must comply with to become ISO 9001 registered, as an international recognized Quality Management System. However, "ISO 9000 Certified" is technically incorrect as ISO 9000 does not have requirements, rather, it means an organization has met the requirements in ISO9001 and defines an ISO 9000 QMS. ISO 9001:2000 was replaced by ISO 9001:2008 in the year 2008, rendering ISO 9001:2000 obsolete. ISO 9001:2008 is focused on meeting customer expectations and delivering customer satisfaction, so one must pay attention to the customer. ISO9001 evaluates whether one's QMS is appropriate and effective, while compelling one to identify and implement improvements.

Continuous improvement assures the customers benefit by receiving products or services that meet their requirements, and that one delivers consistent performance. Internally, the organization will profit from increased job satisfaction, improved morale, and improved operational results (reduced scrap and increased efficiency), while meeting legal and regulatory requirements benefits the community. ISO 9001 does not define the actual quality of the product or service but the standard does help in achieving consistent results and continually improving the process (Oakland, 200:222).

2.2 THE ORIGIN OF ISO 9001:2008

Spencer (2011) argues that ISO standards are developed by technical committees comprising national delegations of experts from business, government and other relevant organizations. They are chosen by the ISO members, i.e., the national

standards institutes participating in the technical committee concerned, and are required to present a national consensus position based on the views of stakeholders in their country.

ISO 9001 has evolved considerably since its inception and now has many more assessors. The ISO 9000 QMS was often seen as separate from the real day-to-day business, but many of the earlier criticisms of the Standard were addressed in the Y2000 update, which moved away from just managing conformance to cover many of the wider issues concerned with managing a business, as well as laying greater emphasis on the key areas of customer focus, people involvement, and, importantly, continuous improvement. A recent update to the Standard was released in late 2008, and the current version to which organizations will be assessed is ISO 9001:2008. However, the changes made in this version were minor and did not significantly affect the actual requirements, the changes being mostly to applicable to a broader range of business types, as was the case up until a few years ago. BS5750, as it was originally known, arose out of production line style manufacturing, this being the predominant industry in the United Kingdom (UK) at that time. This emphasis, however, caused many problems with its use and interpretation when endeavouring to apply it to the service sector type businesses that have proliferated since the 1980s.

In 1987, the BS5750 name was dropped in favour of the international standard, known since by its generic convention ISO9000, and the use of the Standard then spread throughout many other industrialized countries. A significant reason for the rise in registrations in the United Kingdom (UK) was increasing demand by governmental type organizations and civil project contractors that their suppliers be ISO9000 registered. This was intended to guarantee quality, however such did not always happen, as the Standard did not encourage business improvement as such, and, even more seriously, did not say much about customer service. Rather, it was a means of controlling conformance as well as the presumed non-conformities.

It became commonplace for organizations themselves to focus on the ISO 9000 requirements, so much so that they missed the point about satisfying their customers and improving the quality of their products or services. In some cases it

seemed to be more about satisfying the external assessors or auditors. It was not unusual for organizations simply to patch over weaknesses in their ISO 9000 Quality Systems prior to the annual visit by the clarification notes.

There are a range of standards within the ISO 9000 family, but one of particular significance to this study is ISO 9004, which is a very useful guide to implementing ISO 9001, and can help users to understand more fully how to go about ensuring genuine continuous improvement. ISO 9001:2000 was a step in the right direction, and is more relevant to today's service sector industries, however, as with the previous versions the key to ensuring that ISO 9001 delivers actual business benefits and service improvements lies in its implementation.

In the UK, the BS 5750 standards were well on their way to broad acceptance and, in Canada, a series of national standards known as CSA Z299 were also widely used. Other countries with well developed quality management practices, such as Japan, also took a keen interest in the work of the new committee. In addition, experience of military quality assurance specifications, such as the NATO AQAP series and US MIL-SPEC, enriched the sources from which ISO/TC 176 was able to draw.

2.3 ISO 9001:2008 DEFINATIONS AND LEVELS

The Capability Maturity Model (CMM) is used to develop and refine an organization's software development process. It incorporates a five-level evolutionary path of increasingly organized and systematically more mature processes. CMM was developed and is promoted by the Software Engineering Institute (SEI), a research and development centre sponsored by the U.S. Department of Defence (DoD). SEI was founded in 1984 to address software engineering issues and, in a broad sense, to advance software engineering methodologies. More specifically, SEI was established to optimize the process of developing, acquiring, and maintaining heavily software-reliant systems for the DoD. Because the processes involved are equally applicable to the software industry as a whole, SEI advocates industry-wide adoption of the CMM which is similar to ISO 9001, one of the ISO 9000 series of standards specified by the

International Organization for Standardization (ISO). The ISO 9000 standards specify an effective quality system for manufacturing and service industries; ISO 9001 deals specifically with software development and maintenance. The main difference between the two systems lies in their respective purposes: ISO 9001 specifies a minimal acceptable quality level for software processes, while the CMM establishes a framework for continuous process improvement and is more explicit than the ISO standard in defining the means to be employed to that end.

2.3.1 CMM's Five Maturity Levels of Software Processes

There are five levels of maturity in the CMM software processes:

1. At the initial level, processes are disorganized, even chaotic. Success is likely to depend on individual efforts, and is not considered to be repeatable, because processes would not be sufficiently defined or documented to allow them to be replicated.
2. At the repeatable level, basic project management techniques are established, and successes could be repeated, because the requisite processes would have been established, defined, and documented.
3. At the defined level, an organization has developed its own standard software process through greater attention to documentation, standardization, and integration.
4. At the managed level, an organization monitors and controls its own processes through data collection and analysis.
5. At the optimizing level, processes are constantly being improved through monitoring feedback from current processes and introducing innovative processes better to serve the organization's particular needs (Spencer, 2011).

2.4 IMPLEMENTATION OF ISO 9001:2008

Spencer (2011) writes that there is a perception of ISO 9001 as separate that exists outside of the company's and individuals' daily activities, and it is the responsibility of a dedicated individual or group within the company. This is a common concern that is not unfounded, as many companies (especially in the early days of ISO 9001) implemented ISO 9001 with the objective of obtaining a certificate that would allow them access to certain customers or markets. In these cases the management system framework stipulated by ISO 9001 was not understood or considered, rather the focus was on compliance by creating a bunch of documents that would only pass a third party audit. The general staff of the company were not involved in developing the management system and senior management did not intend ISO 9001 to be a management system platform.

To overcome this problem, an organization must focus on developing a management system that provides value to the organization. ISO 9001 registration should be a by-product that validates the system, but not the objective. Individuals at all levels of the organization must be engaged in the implementation process and participate in developing and improving the processes that they own or in which they participate. Process ownership is critical and process owners must be empowered to take control and responsibility for it. Top management has to ensure that the responsibilities and authorities are defined and communicated within the organization. Achieving this is the responsibility of senior management and is a core element of my methodology.

Most profitable companies are doing most that ISO 9001 requires, but not effectively, consistently, or efficiently. Many companies rely on and succeed by the abilities and hard work of their people, as they focus on managing people. However, the focus must be on managing processes. ISO 9001, TQM, Lean, Six Sigma, and others are process management and improvement methodologies, but not one focuses on managing people, rather they address a senior management driven culture of continual improvement.

Prototypes are not part of the general production process and should not be subject to the same process or type of control. Prototypes are typically developed

as part of the design and development process, which must be developed as part of the ISO 9001 implementation. Prototyping can be part of this process or a separate process, as needed. It is important that the ISO 9001-based management system address the unique nature and requirements of the business and customer requirements, while ensuring consistency and control.

At no point does ISO 9001 stipulate how fast the system can or cannot produce a product. It is the processes that one designs and the way they are managed that will allow one to make a product at the speed required by the customer. With this said, ISO 9001 does require that one determines and reviews product requirements from the customer, including delivery requirements, before committing to supply a product (e.g. submission of tenders, acceptance of contracts or orders, and acceptance of changes to contracts or orders).

Appropriate processes should be designed to allow for the identification, prioritization, and processing of “rush” orders, examples of which are sales and contract review, order processing, engineering, production planning/scheduling, and various production processes. A well designed management system will address how ‘rush jobs’ are handled through all of the processes that should support them. This will ensure that they are handled consistently and in turn will ensure that their impact on internal resources (e.g., personnel, material, methods, machines, and money) can be measured and assessed.

From the customer’s perspective, outsourced processes do not absolve a company from the responsibility of ensuring that the outsourced process meets the stated and implied customer requirements. ISO 9001 recognizes this and stipulates that the company must ensure that the purchased product (including outsourced process) conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

This means that one must select suppliers that are capable of living up to the same standards that customers expect. If they cannot, then one must seek a new supplier, work to improve the existing supplier, or develop internal process controls

to ensure that the supplied product or service meets requirements. This is a rather complex issue that deserves a separate detailed discussion.

The system involves poor bureaucracy and has little, if any, business value. However, there are some overheads associated with maintaining a well designed formal management system. Even a mediocre formal management system is able to generate a net gain by offsetting its overheads with improvements in consistency, efficiency, training, quality, problem solving, employee satisfaction, and reductions in errors, rework, customer complaints, returns, and waste.

ISO 9001 does not and will not ensure quality improvement, but does provide a framework and platform for a management system. It describes the minimal elements of a world-class management system, but does not provide guidance on how these elements are to be developed or implemented. Execution is the responsibility of the individual company and its leadership. Being able to identify where quality problems occur is the first step to improvement. The next (after containment) is identifying the root cause of the problem and developing a corrective action that will eliminate the root cause and ensure that a similar problem does not occur again.

Corrective and preventive actions are key elements of continual improvement however, the skills and methods used to effectively identify root cause and to develop robust corrective and preventive actions are not stipulated by ISO 9001. ISO 9001 simply requires that one has a formally defined corrective and preventive action system or process. The root cause analysis and corrective action skill sets and methodologies must be developed or acquired and incorporated into the management system. Process mapping, value stream mapping, regression analysis, and 8D are some examples of the many tools and methods available.

The ISO 9001-based management system was developed for its inherent benefits, and there should be no significant time attributed to maintaining certification. There is a need to invest time, resources, and money in designing and implementing the initial system, but the only time that should be directly attributed to maintaining ISO 9001 certification is that which the management representative spends facilitating the registration and surveillance audit visits.

Top management shall provide evidence of its commitment to the development and improvement of the quality management system and continually improving its effectiveness by:

- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements
- establishing the quality policy
- ensuring that quality objectives are established
- conducting management reviews
- ensuring the availability of necessary resources.

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Improvement can only happen if the management system incorporates improvement processes and elements at the appropriate points and levels, and, more importantly, only senior management can foster a culture and environment of continual improvement.

ISO 9001 certification does not ensure that companies will continually improve, but it can determine if it is or is not improving. Furthermore, at best, consultants can only coach, mentor, encourage, support, educate, transfer skills and knowledge, and introduce tools and techniques. Ultimately it is senior management that must provide the vision, leadership, and resources to continually improve the company and its management system.

The goal of a management system is to define measure, analyze, improve, and control the vast majority of what is done on a daily basis. If customer requirements regularly create scenarios that require deviation from the norm then, by definition, these are not deviations from the norm. In this case the management system must be revised or designed to address how one consistently handles unique scenarios.

Below depicts the implementation of ISO 9001.

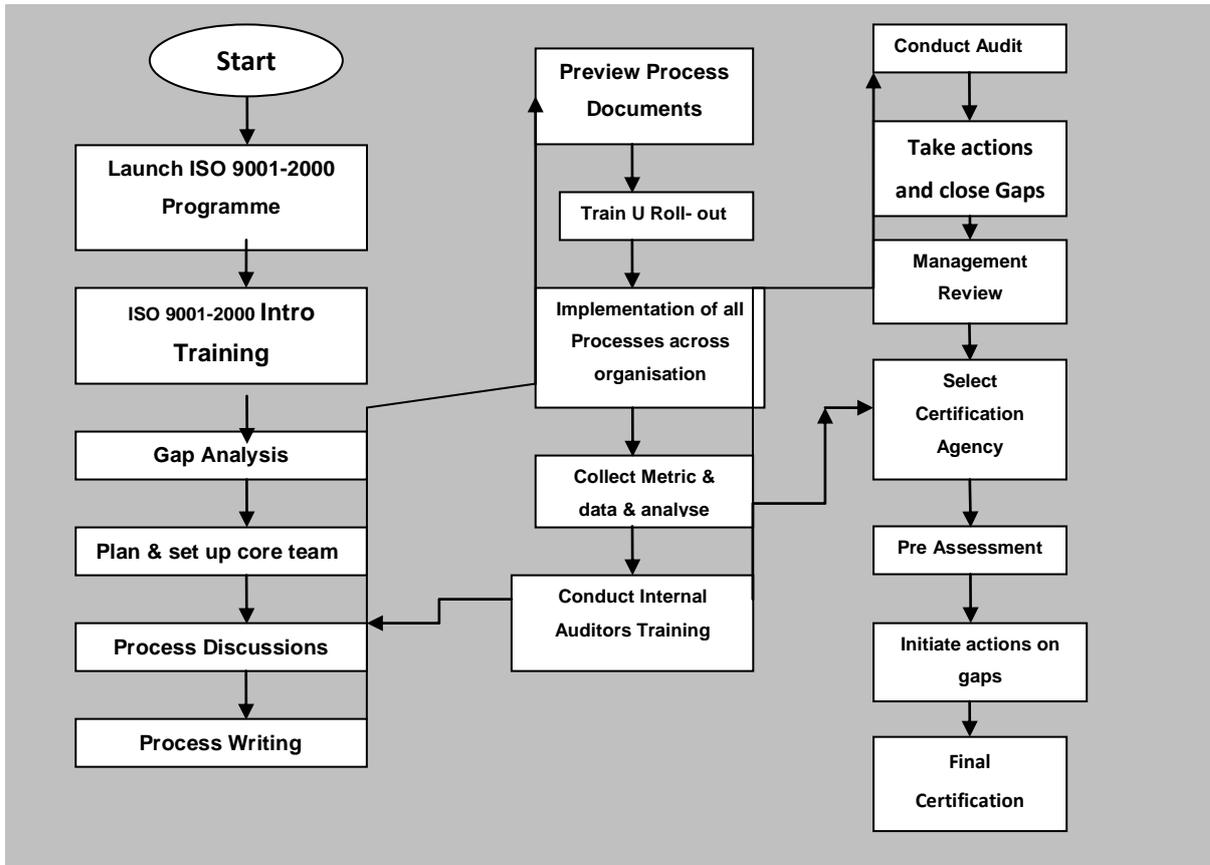


Figure 2.1: The implementation of ISO 9001(Spencer: 2011)

2.4.1. Competitive Advantages of ISO 9001

CEOs and boards of directors are under continually increasing pressure to maintain a competitive edge in everything their organizations do and to achieve complete customer satisfaction and ultimately shareholder satisfaction. Spencer (2011) further explains that to be competitive on a national and a global basis, organizations must adopt a forward thinking approach in developing their management strategies.

International standards force companies to look at their processes in a new light and to take a more active approach to management. For example, if a company

wishes to pursue the new environmental standard, ISO 14000, its environmental management system's pollution control policy will have to be revamped to focus on prevention rather than command-and-control. As the company moves in that direction it will become more competitive, and will do so on a global basis.

2.4.2 ISO 9001: A Key to Global Markets

According to Spencer (2011), first published in 1987 and revised in 1994, ISO 9001 is a series of standards and guidelines related to quality management and quality assurance. Because the standards are neither industry- nor product-specific, they may be used by either manufacturing or service industries, be defined and their processes documented. According to a December 1995 survey by Mobil Inc., more than 130,000 companies worldwide had been registered to ISO 9001.

While ISO 9000 does not specify precisely what kinds of quality processes must occur, or how, it does require that appropriate quality activities in a company consistently adhere to both. ISO 9001 registration does not ensure an organization will become registered to ISO 9001, rather a company must hire an independent third party (known as a 'registrar') to conduct an onsite audit of its operations and verify that it is in compliance with the requirements of the standard. In the USA it is recommended though not required that the registrar be accredited by the Registrar Accreditation Board (RAB). This may not ensure a defect-free or quality product or service, but it does indicate that a basic quality system is in place, and that the registered organization is at least capable of providing its customers with quality products and services (Spencer:2011).

The main strength of the ISO 9001 standards, and the reason they have been adopted worldwide, is that they assure customers who do business with registered firms that fundamental quality systems are in place within those organizations. For many international companies, ISO 90001 is seen as a key to doing business in global markets and improving competitiveness, particularly since for many regulated products in the European Union (EU), ISO 9000 registration is a requirement.

The advantages of ISO 9001 registration, whether perceived or real, are nonetheless marked. For example, in a survey conducted by Dowling College of Long Island, about 41% of ISO 9001 registered companies in the New York City metropolitan area reported an increase in their European market share after registration.

In another survey, conducted by the newsletter Quality Systems Update, approximately 85% of companies claimed they had experienced external benefits as a result of registration to ISO 9001, and 95% noted internal benefits. The most significant external benefits reported in the survey were:

- Higher perceived quality (83.3%)
- Competitive advantage (70%)
- Reduced customer quality audits (56%)
- Improved customer demand (29%).

The internal benefits of registration included:

- Better documentation (88%)
- Greater employee quality awareness (83%)
- Enhanced internal communication (53%)
- Increased operational efficiency and productivity (40%).

One of the major strengths of ISO 9001 is its wider appeal for all types of organization. Its focus on processes and customer satisfaction rather than procedures means it is equally applicable to service providers as manufacturers with greater emphasis on customer satisfaction, process management and measurement, and continual improvement with top management involvement.

2.5 METHODOLOGY

Direct correlation was found between improvements and employee involvement, with improvement and individual goals also being strongly linked. In one pilot project it was found that ergonomic reengineering led to time and cost savings in

manufacturing operations, as well as eliminating employee injury. The improvement change process requires management commitment and action along the lines of employee self interest. A continuous improvement programme must take an integrated approach. Holistic thinking and range of vision are necessary for successful implementation.

2.6 THE PHILOSOPHY BEHIND THE ISO 9001 STANDARD

Kumar (2011) writes that the ISO 9001:2008 standard was designed to provide general guidance on the development of a successful quality system that would deliver quality services and products. Every company is different and the Standard is applicable to everyone from service organizations and trucking companies to design houses and manufacturers. Therefore, the guidelines must be sufficiently flexible to be applied in a variety of business models. In general, the ISO 9001 standard promotes improvements in quality through a consistent, controlled process that continuously achieves improvement. If a process is focused (on the customer requirements) from the top management, controlled consistently and is improving, it will eventually produce high quality results. The Standard does not say when the process will start producing high quality, but rather it depends on many factors.

The Standard contains 8 management principles, which provide the foundation for the ISO 9000 series of standards:

1. Focus on the customer
2. Provide quality leadership
3. Get involvement of people
4. Maintain a process approach
5. Use the system approach to management
6. Continuous improvement (CI)
7. Decisions should be based on facts
8. Maintain mutually beneficial supplier relationships.

These principles are not elements against which the organization can be directly assessed, but rather they are what the ISO believes are the key philosophies of a successful quality-minded organization. They inform the underlying philosophy of the ISO 9001: 2008 and should be considered by any organization wishing to comply fully with the intent of the standard, as well as the content of ISO 9000.

2.7 BENEFITS AND COSTS

There are a number of ISO 9001 benefits and costs to the company, as follows:

2.7.1. Benefits

Procedures and Quality Manual have been designed to work together to address the requirements of the ISO 9001 requirements. This saves time and effort in determining what procedures to have for one's QMS, designing the QMS system, coordinating the procedures, determining how to requirements and document the procedures. Moreover, technical support is available for questions, documentation is professional in presentations, and employees do not have to face a blank page to fill in.

2.7.2. Saving and cost

Cost becomes low because the organization will be saving, and lack of a feeling of ownership for the documentation from the employees.

The internal and external benefits to ISO 9001 implementation are summarized in Table 2.1 (below).

Table 2.1: The internal and external benefits to ISO 9001 implementation

INTERNAL BENEFITS		
Organizational Benefits	Financial Benefits	People Benefits
<ul style="list-style-type: none"> • Improvement of quality of management by down-sizing three functional departments to one and reducing fuzzy management boundaries between individual systems. • Increase in operational efficiency by harmonizing organizational structures with similar elements and sharing information across traditional organizational boundaries. • A voidance of duplication between procedures of systems. • Streamlining paper work and communication. 	<ul style="list-style-type: none"> • Cost savings by the reduction of the frequency of audits. • Reduction in external certification costs over single certification audits. • Increase in margins 	<ul style="list-style-type: none"> • Increase in employee motivation, awareness and qualifications. • Creation of a better company image among employees
EXTERNAL BENEFITS		
Commercial Benefits	Communication /Benefits	Q/E/S Benefits
<ul style="list-style-type: none"> • Improvement of market place. • Gain new customers/satisfy existing ones. • Competitive advantage 	<ul style="list-style-type: none"> • Improvement of company's image. • Improvement of relations with stakeholders. • Evidence of legal compliance 	<ul style="list-style-type: none"> • Improvement in quality, environmental and health and safety. • Reduction of hazardous waste generation. • Reduction of equipment damage and product loss

2.8 CHALLENGES FOR ISO IMPLEMENTATION

The ability of a company to say "ISO 9001 certified" is a requirement for many industries, and has become important for an increasing number of industries whose products include services as well as manufactured products. The ISO 9001:2000 standard contains the requirements for a QMS designed to insure that a company's products meet its customer's expectations, however, successfully implementing the Standard brings challenges.

The internal and external barriers to ISO 9001 implementation are summarized in Table 2.2.

INTERNAL BARRIERS		
Resources	Attitudes/Perceptions	Implementation
<ul style="list-style-type: none"> • Lack of financial resources. • Lack of management and/or staff knowledge, skills and training. • Lack of employee involvement/motivation. • Lack of management and/or staff time 	<ul style="list-style-type: none"> • The change appears too revolutionary/resistance to change. • Low awareness of the benefits. • Other priorities more important. • Perception of bureaucracy. • Short-term orientation 	<ul style="list-style-type: none"> • Cultural differences between disciplines. • Complexity and differences among systems. • High effort for implementation
EXTERNAL BARRIER		
Support /Guidance	Economics	Certifiers/verifiers
<ul style="list-style-type: none"> • Lack of support schemes. • Lack of sector specific implementation tools and examples. • Lack of experienced consultants to assist companies/poor quality information and conflicting guidance. 	<ul style="list-style-type: none"> • Insufficient drivers and benefits. • Uncertainty about the value of IMS in the market place. • Different stakeholders demands 	<ul style="list-style-type: none"> • High costs of Certification/verification. • Duplication of effort between certifiers/verifiers and internal auditors.

Organizations seeking registration to ISO 9001 must be able to execute successfully the following:

- Development of “audit ready” documentation – Solid documentation must include a policy manual, procedures and instructions covering the requirements in the standards with traceability to the stated requirements and objective evidence to confirm that the documentation is being followed.
- Enforce document control – Successful document control means that one can do the following things well: revision control; document access; routing; approval and change impact analysis. Besides control, a document must be easy to find and retrieve by the intended user of its contents.

There are several challenges the organization will face as one starts to document procedures and work instructions. According to feedback, the most difficult aspects for employees involved in documenting the procedures have been:

1. Starting with a blank page
2. Making the different QMS Procedures work together
3. Creating an efficient document control.

Many technical writers and technical writing firms specialize in ISO 9000 documentation, an approach often used in large companies with large amounts of documentation to prepare. A common approach is to have the technical writer interview people responsible for the process and document it. This approach must be combined with incorporating any changes to the process that are being made to comply with ISO 9000. Involving the technical writer in meetings as one plan the changes will help with coordinating the changes and prepared templates or documents.

Templates prepared by the organization or an outside organization can be very helpful to employees. To do so one develops a standard format that one wishes to use for procedures and a format for work instructions. One may also wish to write a work instruction for "Writing a Procedure" and "Writing a Work Instruction". Useful items to include are:

- Definitions for common items such as records, forms and attachments.

- Definitions for procedures and work instruction general writing guidelines. For example, "Start sentences with an action word"; "Include the job title of the person responsible for the action"; and "Provide clear definitions that will help employees create documents that are consistent with other employees' documents and prevent the need for a lot of editing towards the end of your project."

Using a prepared documentation system can save much time and effort if well prepared.

2.9 CHAPTER REFLECTIONS

In the current free market, a market characterized by competition, customers' service expectations are constantly rising, while tolerance for poor quality is declining. Attention to service quality can help an organization to differentiate itself from other organizations and so gain a competitive advantage.

The company in the North West does not have a quality system in place. ISO standards can assist the company and other companies in both manufacturing and service industries to differentiate themselves and their products/services by designing services and products that customers need and will purchase.

The study of The North West company methodology of customer satisfaction highlights the phenomenon that meeting the rising customer expectation has proved to be the most difficult challenges facing service business. Quality is found to be measured most accurately through the customer's eyes, and there will be no improvements unless the customer expectations and perceptions are regularly measured. Measuring customer requirements assists organizations in creating a distinct relationship between what customers want and what the company provides, or a relationship between customer requirements and essential business elements.

2.10 CONCLUSION

ISO 9001 should be led by top management led, which ensures that senior management take a strategic approach to their management systems. Assessment and certification process ensures that the business objectives constantly feed into the processes and working practices to ensure one maximises one's assets. ISO 9001 helps managers to raise the organization's performance above and beyond competitors who are not using management systems. Certification also makes it easier to measure performance and better manage business risk. Evidence shows that the financial benefits for companies that have invested in and certified their QMS to ISO 9001 include operational efficiencies, increased sales, higher return on assets and greater profitability. ISO 9001 ensures that employees feel more involved through improved communication. Continued Assessment visits can highlight any skills shortages sooner and uncover any teamwork issues. The 'Plan, Do, Check, Act' structure of ISO 9001 ensures that the needs of the customer are being considered and met.

The next chapter will present and analysis of the organization's quality system against the principles of the ISO system.

CHAPTER 3

EMPIRICAL ANALYSIS AND INTERPRETATION OF DATA

3.1 INTRODUCTION

An empirical study was undertaken to determine the status of successful ISO: 2008 implementation in a medical company, with the aim of drawing conclusions and making recommendations when linking the theory in Chapter Two with the results of the status of ISO: 2008 implementation in this chapter. The comparison between Chapters Two and Three will form a foundation for the development of a framework (roadmap) for successful ISO implementation, to be presented in Chapter Four. A questionnaire was developed to obtain specific information for ISO implementation, comprising questions relating to the current QMS Practices, QMS Effectiveness, Factors affecting QMS, Leadership, Job satisfaction, Employee morale. (Appendix A).

3.2 RESEARCH DESIGN

The study is designed to find out from a cross-section of the population of a company's employees their knowledge and understanding of the QMS in the workplace. The literature gave valuable insight into the type of instrument to be used to collect data, and for this the closed ended questionnaire was found to be appropriate. According to Kumar *et al.* (2005:132), in a closed-ended questionnaire the possible answers are set out in the questionnaire and the respondents then tick the category that best describes the answer. Section A consisted of bibliographical data, while sections B was about employee perceptions, effectiveness of the current QMS, and leadership, and section C comprised job satisfaction and employee morale questions. Questions in section A focused on the biographical and demographical details in order to establish the nature of the sample, from attributes such as age, gender, occupation, level and

department. Sections B and C were summed up according to a rating scale that focussed on the extent of the respondents' perceptions and attitudes.

3.3 POPULATION AND SAMPLING

According to Leedy *et al.* (2005:183), a sample of the population is surveyed in order to learn about a larger population, therefore a sample of employees in this medical company were investigated in order to gain insight into the QMS in the company. Due to the small number of employees, a convenience sampling method was used, also known as accidental sampling and involving haphazard selection of those cases that are easiest to obtain (Welman, 2005:69). Although this technique of sampling is prone to bias and influences beyond the researcher's control, it is an accepted research method and one appropriate to this study.

Leedy and Ormrod (2005:206) state that convenience sampling makes no pretence of identifying a representative subset of a population but is based on convenience in accessing the sampling. All the departments were involved in this research, yielding a potential total of 102 respondents (N=102).

3.4 DATA COLLECTION

Primary data was collected through the distribution of 200 questionnaires to the people staying in a mine complex belonging to the goldmine under study. A total of 102 were returned, comprising a response rate of 51%. The reason for this low response was due to questionnaire being personally delivered to the hospital. Not all questionnaires were filled in or completed appropriately, thus two were rejected for being incomplete.

Table 3.1: summary of questionnaires issued and returned

Number of questionnaires issued	Number of questionnaires returned	Percentage
200	102	51

Another reason for the low return was that some of the employees were off duty, and due to time constraints more questionnaires could not be collected at the company. Nevertheless, this response rate was considered adequate to achieve reliable and valid conclusions (Anderson, 1990:167).

Based on the sensitivity of the problem to be solved, the respondents tended to hide their true feelings and attitudes and opt to respond according to what was considered to be right or ethical (Kumar *et al*, 2005). In this study it was anticipated that they might feel uncomfortable in expressing their true attitudes about QMS, for fear of appearing unethical or stereotyped, hence, the use of secondary data to substantiate the primary data and establish the actual progress made towards the reaching of the target. This is not triangulation however, since triangulation compares and uses three or more different methods of collecting data, which are then compared to test each other's accuracy (Welman *et al.*, 2005:194). The response was received and calculated.

3.5 DATA ANALYSIS

The North West University (Potchefstroom Campus) statistical consultation services were utilized. It used the SAS (SAS Institute Inc. 2003) programme which reflected statistical measures such as frequencies, central tendencies (mean scores), variability (standard deviation), reliability and validity (Cronbach's alpha) and the correlational measurements (phi coefficient). Due to the limitations discussed below, only the frequencies, mean scores and standard deviations, presented in the form of tables were used in the interpretation of the primary data. Each table was followed by an analysis and interpretation of data.

There were three sections with the following aims: Section A: to determine biographic and demographic information of all employees in the company. Section B: to determine the measurable QMS perceptions and this includes QMS effectiveness, QMS leadership. Section C: to determine the measurable employee feelings about job satisfaction and employee morale.

Table 3.2 below summarizes the Cronbach Alpha Coefficient results:

Variable	Cronbach Alpha Coefficient
QMS Perceptions	0.88
QMS Effectiveness	0.942
QMS Leadership	0.931
Job Satisfaction	0.815
Employee Morale	0.767

The above table (Table 3.2) indicates that the reliability of the instrument was moderate, and according to Pietersen and Maree (2007: 216), such reliability estimates are regarded as acceptable.

3.6 ADMINISTRATIVE PROCEDURES

A number of administrative procedures were incorporated into the data gathering process.

3.6.1 Section A: Biographic and Demographic Information

The demographic information is summarised in Tables 3.3. (below).

Table 3.3: Summary of Biographic and Demographic Information:

ITEM NO	QUESTION	CATEGORY	PERCENTAGE
1	GENDER		
		Male	13
		Female	87
2	AGE		
		20 - 30	30.7
		31 - 40	26.7
		41-50	26.7
		50+	15.8
3			
	OCCUPATION	Accountant	1.0
		Registered Nurse	44.6
		Nurse	26.7
		Admin Officer	19.8
		Electrician	2.0
		Driver	1.0
		Other	5.0
4	LEVEL	Manager	3.3
		Matron	1.1
		Supervisor	13.3
		Other	82.2
5	DEPARTMENT	ICU	16.5
		Theatre	3.1
		Finance	7.2
		Maintenance	2.1
		Other	71.1

✓ **Gender**

From the above question item 1, 13% of respondents were male and 87% female, reflecting its being a private medical company, hence most of employees are females.

✓ **Age**

The finding that 30.7% of respondents were between 20 and 31 years of age shows that this age group was the largest, followed by 31 to 40 and 41 to 50, with 26.7 % each. 15.8% of the correspondents were over 50 years of age, showing that the company had mature employees who were experienced.

✓ **Occupation**

Item 2 shows that majority of employees in this company were registered nurses (44.6%), and some 26.7% of non-registered nurses. The minority of employees were in administration, maintenance and other disciplines, reflected in the ability of a high number of respondents to understand and interpret the questionnaire.

✓ **Level**

The information from the table indicates that 3.3% of respondents were managers, and significant number (13.3%) supervisors. By deduction, 82.2% of respondents fell under other categories.

✓ **Department**

The findings show that most of the respondents were on the wards, appropriate for a medical company. 16.5% worked on the Intensive Care Unit (ICU) and 3.1% in the operating theatre. 71.1 % were in other departments.

3.6.2 Responses to QMS Perceptions

In sections B and C the respondents had to indicate their opinions by marking a cross in the applicable box, and the following scale was used:

1. Strongly disagree
2. Agree
3. Disagree
4. Strongly agree

The aim of Section B was to measure employees' perceptions of quality. QMS perceptions were to be determined in this section, divided into three categories, namely QMS perceptions, QMS effectiveness, and QMS leadership. Section C was to measure the employees' feelings towards their work-related needs and included questions about job satisfaction and employee morale. The means of these categories, with measurement of respondents' perceptions of quality and their feelings towards their work-related needs are summarized in Table 3.4:

Table 3.4: The Mean

Category	Mean
QMS Perceptions	1.87
QMS Effectiveness	1.91
QMS Leadership	2.01
Job Satisfaction	1.89
Employee Morale	1.97

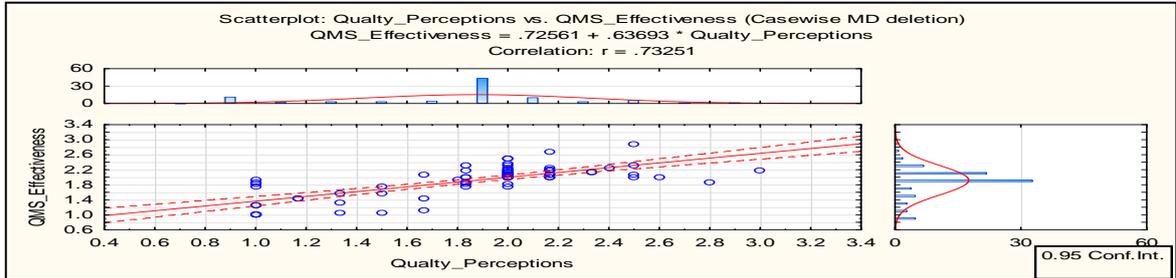
3.7 LIMITATIONS OF THE STUDY

This research must be read or referred to with several limitations borne in mind. The size of the sample with regards to the entire population was small, therefore it prevented the use of other statistical techniques such as factor analysis. The Cronbach's alpha value used for measuring reliability was found to be outside the accepted specifications of 0 to 1. Due to the time limitations, only one cross-sectional study was performed. A longitudinal study would have been more useful to verify the truthfulness of the results. A convenient sample was used, which is prone to bias, therefore sometimes might not be a true representative or reflection of the population.

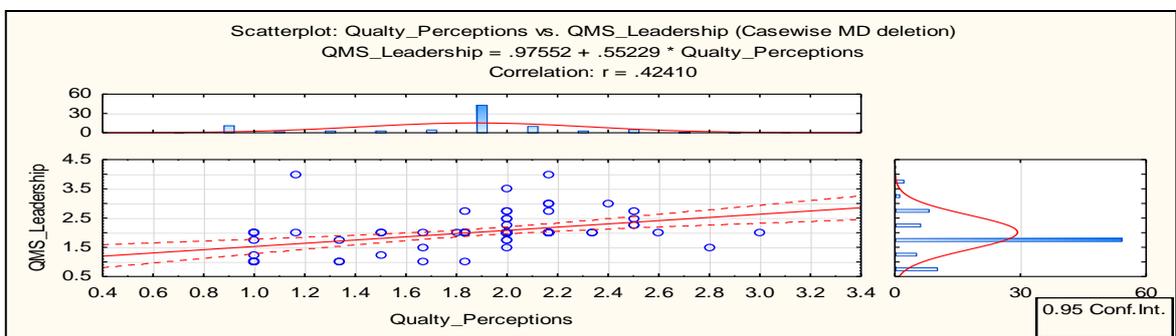
3.8 DISCUSSION

The following graphs show quality perceptions of aspects of QMS:

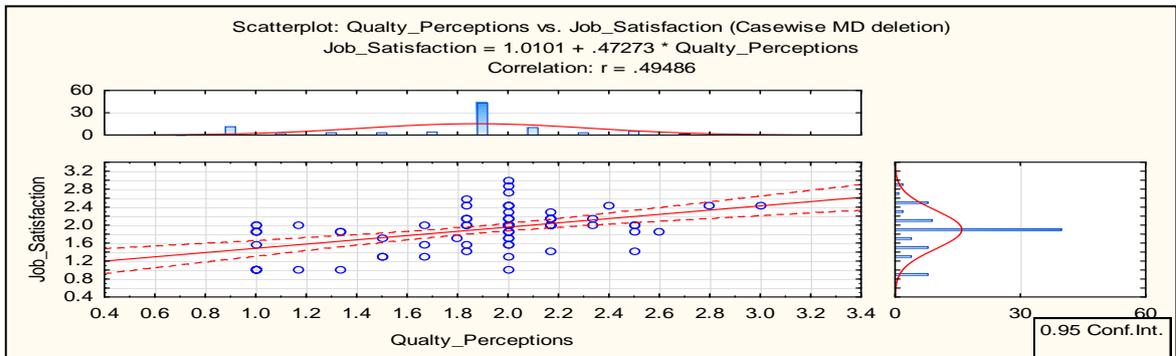
Graph 1



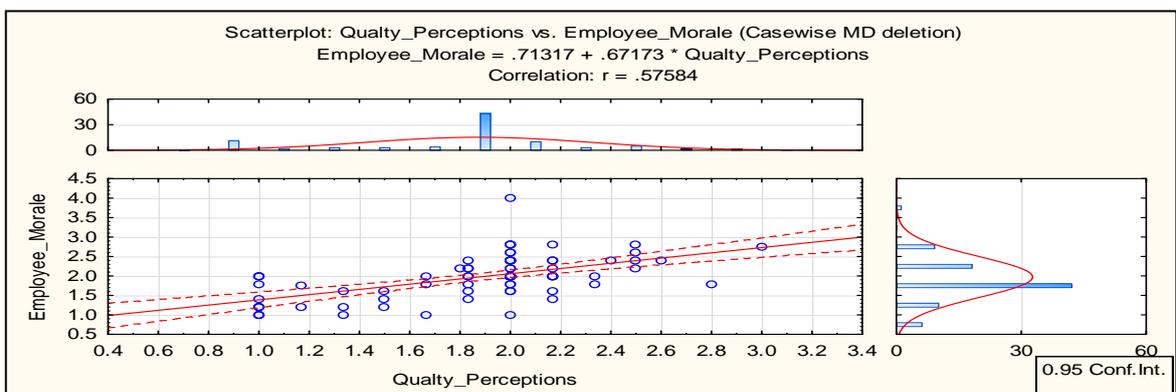
Graph 2



Graph 3



Graph 4



Section A: QMS practices effectiveness

The majority of the respondents were female and/or between the ages of 20 and 31. This is important because it has an impact on the way the various groups viewed the concepts of life or behaviour, i.e., due to their life experiences the younger generations view life differently from the older generations. Most of the respondents were professional nurses.

The section was measuring the employee perceptions with regards to continuous improvement, quality design, and evaluation of business strategies in the company. It had six questions, with which 90% of respondents agreed and 10% disagreed.

Section B: QMS general effectiveness

The questions in this section related to top management commitment, documentation of quality policy and objectives, records of documents and practices, communication, work environment and team spirit. The section had 16 questions, with 70% of the respondents agreeing that the QMS in the company was effective. 25% of respondents strongly agreed, while 5% disagreed.

Section B: Leadership QMS

The section was about management involvement and effective quality leadership. This section had four questions, and 17% of the respondents strongly agreed that there was effective QMS leadership. 66% of the respondents agreed, while the remainder (17%) disagreed.

Section C: Job Satisfaction

This section measured the feelings of employees towards their work related needs. It entailed employee training, records of training, skills and experience. The section had seven questions, and 88% of the respondents were satisfied with their jobs and 12% were not happy or satisfied.

Section C: Employee Morale

This section related to employee involvement in planning, goal setting, encouragement, dedication, improvement and rewarding. The majority of respondents (50%) agreed, with 21% strongly agreeing and 29% disagreeing.

3.9 CONCLUSION

In summary, the QMS in the hospital was effective but the employee morale was low. The company must conduct a gap analysis and implement a more effective system for improved results.

CHAPTER 4

ISO 9001:2008 CERTIFICATION AND IMPLEMENTATION

4.1 INTRODUCTION

ISO 9001 is an international quality management standard that is rapidly becoming the most popular in the world. Thousands of organizations in over 150 countries have adopted it, and many more are in the process of doing so, because it controls quality and saves money.

The International Organization for Standardization (ISO) is located in Switzerland and was established in 1947 to develop common international standards in many areas. Its members come from over 150 national standards bodies. ISO 9001 is important because of its orientation. While the content itself is useful and important, this alone does not account for its widespread appeal, rather it is the international orientation. Currently, ISO 9001 is supported by national standards bodies from more than 150 countries, which makes it the logical choice for any organization that does business internationally or that serves customers who demand an international standard of excellence. ISO 9001 is also important because of its systemic orientation, considered by some as crucial.

Many wrongly emphasize motivational and attitudinal factors, the assumption being that quality can only be created if workers are motivated and have the right attitude. This is a valid point but does not go far enough. Unless one institutionalizes the right attitude by supporting it with the right policies, procedures, records, technologies, resources, and structures, one will not achieve the standards of quality that other organizations seem to be able to achieve. Unless one establishes a quality attitude by creating a quality management system, one will not achieve a world-class standard of quality. Simply put, if one wishes to have a quality attitude one must have a quality system, which is what ISO recognizes, and what makes ISO 9001 important.

4.2 QMS IMPLEMENTATION STRATEGY

According to Baroniene (2005:15-21), after the implementation of management systems, organisations become more oriented to targeted criteria, react more operatively to the changing internal and external conditions and become more open to innovation. Successful implementation of innovative quality management methods provides the opportunity to adapt better to changing conditions and to different innovations. Research has shown that the implementation of management systems (based on 9000 family standards) impacts not only on the specifics of workers intercommunication but also on the thinking and ways of getting the job done (by Baroniene, 2005:15-21).

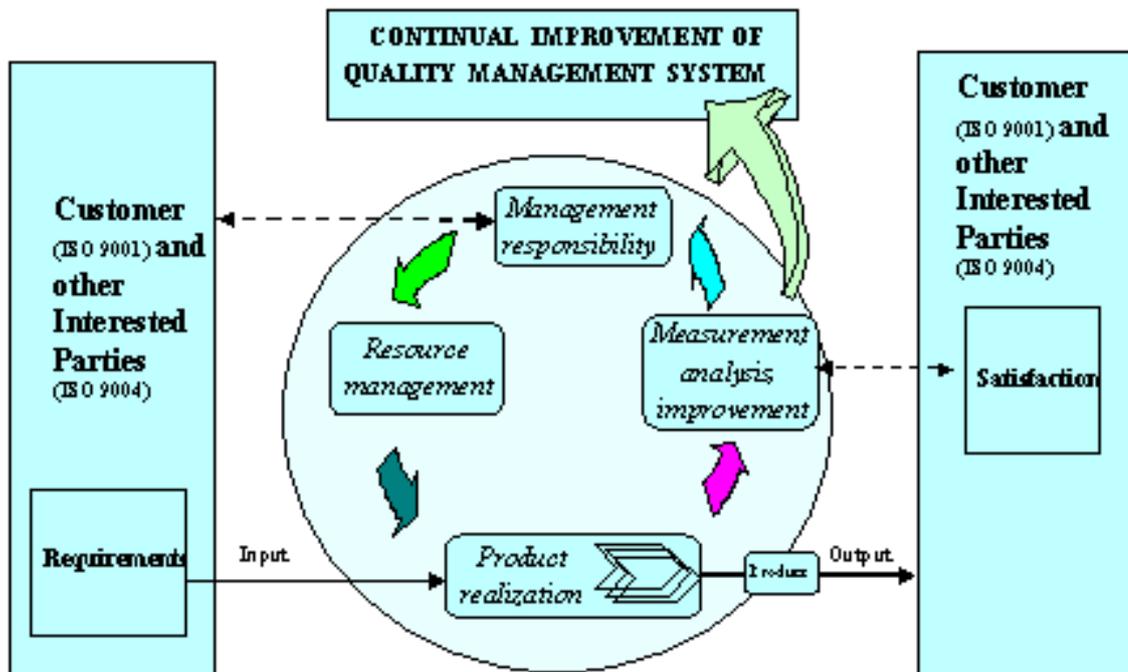
Cochran (2011), states that leadership by top management is a primary theme of ISO 9001:2000. Section 5 of the standard “Management Responsibility” is notable for the first three words of each of its subsections: “top management shall,” which places the responsibility for carrying out the requirements squarely on the shoulders of top management.

According to Lisai (2007:68), there are no right answers on how to implement a QMS in an organization, but rather it depends primarily on several factors such as the vision, attitude and commitment among top managers and employees, and the introduction of continuous education for enhancing fundamental skills and knowledge of quality improvement within the organization. The process mapping step is a critical phase, and the key is to find and then implement the new concept as well as its effects in terms of both productivity and physical and mental burden on the employees.

4.3 THE PROCESS OF IMPLEMENTING A QMS

According to Zolghadar (2004:35), within the ISO norm there is a process model described as combining measurement, analysis, improvement and the responsibility of the leadership in a control cycle. The model is graphically depicted in Figure 4.1:

Figure 4.1: Process Model. Zolghadar (2004:35)



Zolghadar (2004:35) states that with regard to the measurability and assessment of processes, the norm calls for the determination of criteria and methods in order to be able to conduct and direct the processes. The company in turn is compelled to measure, monitor and analyse the processes. Furthermore, the company has to make arrangements to achieve the planned goals as well as continuous improvement of processes.

Hegenus (2007:3) describes the model in terms of the following aspects:

- It can be used for organizational design and re-design
- Processes enable strategies to be fulfilled
- Processes precede structure in a (re)design effort

- Culture and business results are outcomes of the business operations model
- Technology enables process and is influenced by structure
- The human performance components (structure, development systems, reward systems and decision-making systems) are a significant part of the business operations model.

According to Henrichs and Aden (2001:1-2), in accordance with ISO 9000, quality management consists of the following activities:

- **Quality policy** - Establishing overall quality related intentions and goals of an organisation
- **Quality planning** - Setting quality objectives and specifying processes and resources necessary to fulfil these objectives
- **Quality control** - Executing processes to fulfil quality requirements
- **Quality assurance** - Providing there is, confidence these quality requirements will be fulfilled
- **Quality improvement** - Increasing the ability to fulfil quality requirements.

4.4 THE APPROACH TO EFFECTIVE IMPLEMENTATION OF QMS

According to Johnston (2002:3-4), in order to map the ISO 9001:2000 standard, a gap analysis would be required to detail exactly what is necessary to meet the requirements of the standard. It helps to identify any gaps that exist between the standard and the existing business model or processes. Once the gaps are identified, steps need to be taken to fill those gaps and improve the overall performance of processes within the organization. The author states that the process is initiated with a plan, followed by carrying it out then checking and analyzing what was done. An improvement would follow, based on any weaknesses found.

Johnston (2002:4) defines a process as, “a series of actions that result in an outcome”. When all processes are combined, a system has been developed and must be managed in order to achieve the organizations goals. According to Richter and Dibbern (2005:3), the principle of “process approach” is defined as, “the management of activities and related resources in a process to efficiently achieve the desired result”. For product realisation, organizations need a defined purpose and goal or objective. There should be a pool of resources available in the form of tools, equipment, machinery, money, people and knowledge to support the process development. The authors state that the output of a process, which is in the form of a product, information, people or decision, needs to be controlled by standards, measurements and feedback loops. The process is characterized by results as a measure of achievement, efficiency and effectiveness.

Stankeva (2008:2) argues that internal audits should be conducted with the main purpose of evaluating progress and level of implementation of the QMS in the respective departments. Another purpose is to have a prepared report on the progress of the QMS in respective departments, for a review of the QMS activities by top management once scheduled. The author states that if the audits are reassuring that the QMS functions properly in departments, and then the organization will be able to apply to the Certifying Authorities. The operating procedures on production planning and management as well as those on monitoring, testing and analysis should already be finalised.

Mohammed and Asmoni (2006:2) state that some of the obstacles to implementation of a QMS include misconception of the ISO 9000 quality system as something secondary to the business. In addition, the scheme may have appeared too complex and there may have been lack of understanding of the ISO 9000 quality standards. It can have a high cost, especially the initial one, and a loss of productivity of the workforce due to the effort exerted in learning and implementing the new system. This is in addition to the irregular duties, and absence of special regulation that makes it incumbent upon contracting companies to establish and implement QMS. Matters are worsened if there is no encouragement from the certain industry clients. Finally, it is difficult to apply to some industries, such as construction.

According to Lacalamita (2008:1), the declared end points of quality certification to the achievement of several key objectives are as follows:

- The realization of a “quality path” inside the organization
- The realization of a common platform of “knowledge management” among all managers
- The creation of a “common team spirit” based on team job and on the direct participation of their results
- The development of special attention to customer expectations with special regards to the scientific community
- The development of inter-functional activities through a process approach.

4.5 ASSESSING THE SUCCESS OF IMPLEMENTING A QMS

According to Conrad, Deubel, Kohler, Sören, and Christian (2007:1), despite the fact that the number of organizations introducing and maintaining certified QMSs have been constantly growing, an increasing number of reports about quality problems, defective products and product call-backs are being encountered. Still, failures occur and there must be reasons. Possible explanations therefore could be:

- The use of inadequate and insufficient tools or methods within the QMS
- The tools or methods in use are not integrated sufficiently deeply in the processes
- The tools or methods in use are applied in an inadequate or wrong way
- The tools or methods, or even the QMS itself, are not accepted or supported by the company’s staff
- There are still processes or process steps that are susceptible to failure.

Kleinsorge and Haas (2004:7) argue that quality can be determined either through subjective or objective assessment criteria. In the corporate sector especially, the

term “quality” is strongly related to a technical viewpoint. It is equated with high technical performance, a proper firmness, durability and faultless functions. The author states that the level of quality is based on how technical norms and specifications are met, and this is *objective*. However, when considering service a subjective assessment criterion is necessary. In the context of performance the user of a product is the main source of quality assurance as they express their satisfaction with a product. In this regard, the elaboration on “fitness for use” is the benchmark and centre of quality assessment, which becomes *subjective*.

According to Chawane, Van Vuuren and Roodt (2003:62), organizational underperformance is influenced by a lack of insight and commitment to change programmes, organizations that are not capable of learning, inflexible management thinking, neglect of the development of employees, and a lack of trust in workplace relationships. These do not reflect the principles of fairness and organizational integrity, resulting in incongruent personal and organizational outcomes.

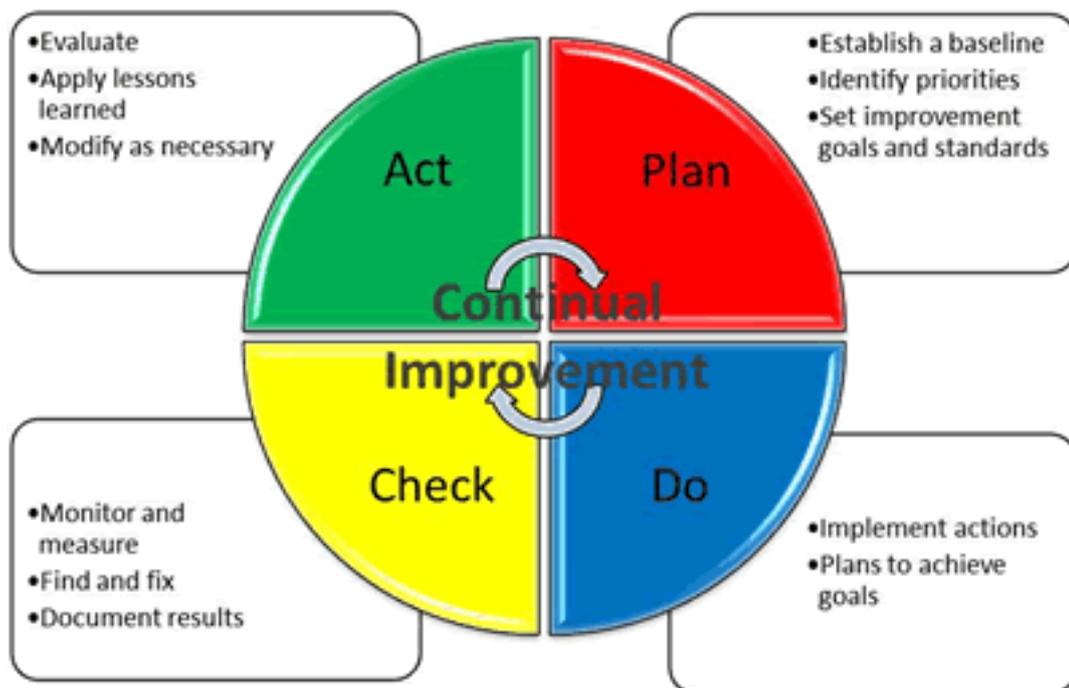
Chawane *et al.* (2003:62, citing Czander, 1993), state that management frequently responds by increasing control, making threats and/or introducing reward schemes which are designed to force and/or entice employees to keep on working. The authors view organizational strategies employed to diffuse the defensive routines as a source of frustration rather than satisfying individuals’ needs. Since individuals’ needs are dominant, employees may undermine the organization’s tasks to obtain self gratification.

According to Rao (2008:9), among the most widely used tools for continuous improvement is a four-step quality model referred as the PDCA cycle (see Figure 3.6, below) which denotes Plan, Do, Check and Act:

- **Plan:** Identify an opportunity and plan for change
- **Do:** Implement the change on a small scale
- **Check:** Use data to analyse the results of the change and determine whether it made a difference

- **Act:** If the change was successful, implement it on a wider scale and continuously assess your results. If the change did not work, begin the cycle again. The Quality Model is depicted below:

Figure 4.2: Plan-do-check-act cycle Rao (2008:9)



4.6 THE INFLUENCE OF QUALITY IN RELIABILITY AND PERFORMANCE

According to Rao (2008:54), another important issue in quality is the concept of reliability and the relationship between quality and reliability with belief that a high quality system generally has greater reliability. The reliability of a product or system conveys the concept of dependability, successful operation or performance, and absence of any failure. The author states that failure or mechanism of failure in a system is associated with the quality of a product. Quality denotes conformance to specifications, whereas reliability denotes absence of failure during operational phase of the product. The reliability is a statistical parameter based on failure rates, amongst other factors, which predicts the probability that the system will work without failure in the given environment.

According to Moodliyar (2008:5), organizations are required to identify areas of improvement on their QMS with an aim of increasing customer satisfaction. The information gathered from performance measurement of processes and customer satisfaction can be used to identify areas of improvement. The author believes the outcome as likely to be a success if the approach is viewed as a way to improve internal efficiencies.

Moodliyar (2008:7), states that organizations should include employees in the documenting process instead of a response to external pressure from customers or governmental bodies. Involvement of employees in the process of gaining certification enhances the outcome and success.

Conclusions and recommendations in Chapter Five will benefit the medical company in the North West and help to successfully implement one of the popular and powerful QMS, ISO 9001:2008. This will benefit the company with regards to good customer relationship, increased productivity, increased return on investment (ROI), and job satisfaction.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

ISO 9001:2008 is a powerful quality management tool that when implemented and applied correctly can impact positively on performance, processes, outcomes, and ultimately improve the company's revenue or reduce costs. The aim of this chapter is to draw conclusions that will be based on the information gathered during the literature study, the survey study and the integration of these results. The study offers the critical factors or elements to the success of ISO 9001 implementation presented in a framework (roadmap). The quality management components that are important to consider when implementing are: commitment of top management, change management principles, effective communication and alignment of goals and resources. Considering these components, certain recommendations will be made in respect of successful implementation of ISO 9001.

5.2 CONCLUSIONS

To implement a ISO 9001:2008 QMS that will help the organization increase customer satisfaction and continuous improvement, the SME must overcome several critical challenges, including a short-term perspective of top management, the pressure to gain ISO 9001 certification as soon as possible, over-reliance on external consultants, lack of spending on internal training, lack of QMS planning, and a product rather than a process focus

There are many issues that must be addressed in moving the QMS from the initial state to the desired state. For example, all organizations implementing ISO 9001 will need to consider the unique culture within the organization, its size, and the resources available. Beyond those widely discussed points, three issues that merit

particular attention are: consideration of the QMS as a parallel function, training, and auditing. A wide variety of methodologies and techniques have been used to implement ISO 9001, however, its successful implementation in a company can be elusive. One of the key reasons for this is that many companies overlook the complexity of the implementation processes and the organizational changes that are needed to ensure the QMS is fully functional. A fully functional QMS leads to increased customer satisfaction and continuous improvement in business results.

Although the existence of documentation is a key requirement of a functional ISO 9001 QMS, it is not in itself sufficient. To develop and implement a fully functional one, it is essential that a SME correctly identifies the initial state of its QMS and the path it will follow to achieve the desired state. The explicit identification of the initial states and paths will help managers within companies to understand the process of implementing ISO 9001 and the fundamental issues that they must address. This should help companies to prevent implementation failures within their companies.

5.3 RECOMMENDATIONS

According to Greg (2011), the integration is largely a function of how well the QMS manages to share information with other subsystems and its ability to align with the policies, norms, goals, and values in place throughout the organization. In most companies, training and staff development is more likely to be *ad hoc* and small scale because of modest human and financial resources and the absence of a specific training budget. To prevent the problems arising from lack of education and training, two actions are recommended:

- **Education of Top Management:** The centralization of decision making processes within many companies means that the management cans either be the main stumbling block to change or the main catalyst for change. Therefore, any approach to ISO 9001 implementation must involve considerable education for the top management of the organization to create awareness and understanding of the implementation process as a

change initiative. Implementing a fully functional and documented QMS requires motivation by top management to appreciate, achieve, and implement the necessary measures to meet the standards' criteria.

- **Education and Training of Employees:** companies are often under pressure to quickly gain ISO 9001 registration. Meeting the requirements of the standard in a short period of time can prove a formidable obstacle for a small company. Since most companies do not possess the necessary expertise internally, they may be inclined to hire external experts to provide the necessary technical expertise and manpower. However, having a functioning and documented QMS requires more than that, in particular assurance that all employees clearly know what is expected of them and how they can contribute to the attainment of their organization's goals. This will likely require the preparation and implementation of a training plan tailored specifically to the unique characteristics and maturity level of the company.
- **Audits:** A QMS is not going to produce the expected results unless it is fully functional. While auditing must therefore verify the existence of the necessary documentation, it must also focus on the functionality of the QMS. The measurement of the functionality and the qualitative and financial impacts of QMS have been the subject of several studies. Included among the categories used to measure functionality and performance improvement, two are particularly noteworthy for our purposes: management commitment and employee involvement. A QMS cannot be functional in the absence of those two characteristics. Therefore, as a minimum, internal and external auditors should continually verify top management's commitment to increased company-wide quality awareness and improvement in addition to employee involvement in the design, implementation, operation, and improvement of quality related processes and procedures.

5.4 IMPLEMENTING ISO 9001 QMS

Implementation of ISO 9001 affects the entire organization from the start. If pursued with total dedication, it results in 'cultural transition' to an atmosphere of continuous improvement.

The process of implementing ISO 9001 depends on the:

- sophistication of the existing quality programme
- size of the organization
- complexity of the process.

The 14 essential steps, briefly described below, are to be followed through for successful implementation of the ISO 9001 quality management system.

Step 1: Top Management Commitment

The top management (managing director or chief executive) should demonstrate a commitment and determination to implement an ISO 9001 QMS in the organization. Without top management commitment no quality initiative can succeed. Top management must be convinced that registration and certification will enable the organization to demonstrate to its customers a visible commitment to quality. It should realize that a quality management system would improve overall business efficiency by elimination of wasteful duplication in management system.

The top management should provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements
- defining the organization's quality policy and making this known to every employee

- ensuring that quality objectives are established at all levels and in all functions
- ensuring the availability of resources required for the development and implementation of the quality management system
- appointing a management representative to coordinate quality management system activities
- conducting management review.

The top management should also consider actions such as:

- Leading the organization by example
- Participating in improvement projects
- Creating an environment that encourages the involvement of people.

This type of top management commitment may be driven by:

- **Direct marketplace pressure:** requirements of crucial customers or parent conglomerates
- **Indirect marketplace pressure:** increased quality levels and visibility among competitors
- **Growth ambitions:** desire to exploit market opportunities
- **Personal belief in the value of quality** as a goal and QMSs as a means of reaching that goal.

The top management should identify the goals to be achieved through the quality management system. Typical goals may:

- Be more efficient and profitable
- Produce products and services that consistently meet customers' needs and expectations
- Achieve customers satisfaction
- Increase market share
- Improve communications and morale in the organization

- Reduce costs and liabilities
- Increase confidence in the production system.

Step 2. Establish Implementation Team

ISO 9001 is implemented by people. The first phase of implementation calls for the commitment of top management - the Chief Executive Officer(CEO) and perhaps a small number of other key people. The next step is to establish an implementation team and appoint a Management Representative (MR) as its coordinator to plan and oversee implementation. Its members should include representatives of all functions of the organization, including Marketing, Design and development, Planning, Production, and Quality control. In the context of the standard, the MR is the person within the organization who acts as interface between organization management and the ISO 9001 registrar. However, his or her role is much broader and he or she should also act as the organization's "quality management system champion," and be a person with:

- complete backing from the CEO
- genuine and passionate commitment to quality in general and the ISO 9001 quality management system in particular
- the dignity - resulting from rank, seniority, or both - to influence managers and others at all levels and in all functions
- detailed knowledge of quality methods in general and ISO 9001 in particular.

The members of the implementation team should also be trained on ISO 9001 QMSs by a professional training organization.

Step 3. Start ISO 9001 Awareness Programmes

ISO 9001 awareness programmes should be conducted to communicate to the employees the aim of the ISO 9001 QMS; the advantage it offers to employees, customers and the organization; how it will work; and their roles and responsibilities within the system. Suppliers of materials and components should

also participate in these programmes, which should emphasize the benefits that the organization expects to realize through its ISO 9001 QMS. The programme should also stress the higher levels of participation and self-direction that the QMS renders to employees. Such a focus will go far to enlist employee support and commitment. The programmes could be run either by the implementation team or by experts hired to talk to different levels of employees.

Step 4. Provide Training

Since the ISO 9001 QMS affects all the areas and all personnel in the organization, training programmes should be structured for different categories of employees, e.g., senior managers, middle-level managers, supervisors and workers. The ISO 9001 implementation plan should make provision for this training, which should cover the basic concepts of QMSs and the standard and their overall impact on the strategic goals of the organization, the changed processes, and the likely work culture implications of the system. In addition, initial training may also be necessary on such aspects as writing quality manuals, procedures and work instruction; auditing principles; techniques of laboratory management; calibration; and testing procedures. When in-house capacity to carry out such training is unavailable, it may be necessary to participate in external training courses run by professional training organizations. Alternatively, an external training institution could be invited to conduct in-house training courses.

Step 5. Conduct Initial Status Survey

ISO 9001 does not require duplication of effort or redundant system. The goal of ISO 9001 is rather to create a quality management system that conforms to the standard. This does not preclude incorporating, adapting, and adding onto quality programmes already in place. The next step in the implementation process is therefore to compare the organization's existing QMS, if there is one, with the requirements of the standard (ISO 9001:2008).

For this purpose, an organization flowchart showing how information actually flows (not what should be done) from order placement by the customer to delivery to this

customer should be drawn up. From this overall flowchart, a flowchart of activities in each department should be prepared, and with the aid of the flowcharts a record of existing quality management system established. A significant number of written procedures may already be in place and unless they are very much out of date these documents should not be discarded, rather, they should be incorporated into the new quality management system. Documents requiring modification or elaboration should be identified and listed. This exercise is sometimes referred to as "gap analysis." During these review processes, wide consultation with executives and representatives of various unions and associations within the organization is required to enlist their active cooperation. In the review process, documents should be collected, studied and registered for further use, possibly after they have been revised.

Before developing new QMS documentation, one should consider with which quality requirements or department to start. It is advisable to select an area in which processes are fairly well organized, running effectively and functioning satisfactorily. The basic approach is to determine and record how a process is currently carried out, which can be done by identifying the people involved and obtaining information from them during individual interviews. Unfortunately, it often happens that different people will give different, contradictory versions of a process, each referring to oral instructions that are inaccurate or unclear. This is why the points are often not described factually the first time around, and have to be revised several times.

Once agreement has been reached on how to describe the current process, this has to be adapted, supplemented and implemented according to the requirements of the quality standard (ISO 9001:2008). This requires organizational arrangements, the drawing up of additional documents and possible removal of existing documentation (e.g., procedures, inspection/test plans, inspection/test instructions) and records (e.g., inspection/test reports, inspection/test certificates). In introducing a QMS, the emphasis is on the improvement of the existing processes or the re-organization of processes.

In general, the steps to follow are the following:

- Ascertain and establish the following: What is the present operation/process? What already exists?
- Analyze the relevant sections of the quality standard, ISO 9001:2001. What is actually required?
- If necessary, supplement and change operational arrangements in accordance with the standard, develop documents and records, and describe operations/ processes.

Step 6. Create a Documented Implementation Plan

Once the organization has obtained a clear picture of how its quality management system compares with the ISO 9001:2008 standard, all non-conformances must be addressed with a documented implementation plan. Usually, the plan calls for identifying and describing processes to make the organization's QMS fully in compliance with the standard.

The implementation plan should be thorough and specific, detailing:

- Quality documentation to be developed
- Objective of the system
- Pertinent ISO 9001:20008 section
- Person or team responsible
- Approval required
- Training required
- Resources required
- Estimated completion date.

These elements should be organized into a detailed chart, to be reviewed and approved. The plan should define the responsibilities of different departments and personnel and set target dates for the completion of activities. Once approved, the Management Representative should control, review and update the plan.

Step 7. Develop Quality Management System Documentation

Documentation is the most common area of non-conformance among organizations wishing to implement ISO 9001 QMSs. As one company pointed out:

When we started our implementation, we found that documentation was inadequate. Even absent, in some areas. Take calibration. Obviously it's necessary, and obviously we do it, but it wasn't being documented. Another area was inspection and testing. We inspect and test practically every item that leaves here, but our documentation was inadequate.

Documentation of the QMS should include:

- Documented statements of a quality policy and quality objectives
- A quality manual
- Documented procedures and records required by the standard ISO 9001:2000
- Documents needed by the organization to ensure the effective planning operation and control of its processes.

Quality documentation is generally prepared in the three levels, as indicated in the box below. Use ISO 10013:1995 for guidance in quality documentation.

Level A: Quality manual

- States the scope of the quality management system, including exclusions and details of their justification; and describes the processes of the QMS and their interaction. It generally gives an organization profile; presents the organizational relationships and responsibilities of persons whose work affects quality; and outlines the main procedures. It may also describe the organization's quality policy and quality objectives.

Level B: Quality management system procedures

- Describes the activities of individual departments, how quality is controlled in each department and the checks that are carried out.

Level C: Quality documents (e.g., forms, reports, work instructions)

- Work instructions describe in detail how specific tasks are performed; include drawing standards, methods of tests, and customer's specifications.
- Presents forms to be used for recording observations.

In small companies, the above levels of documentation could be presented in one manual; otherwise, separate manuals should be prepared.

A list of the documents to be prepared should be drawn up and the responsibility for writing them assigned to the persons concerned in various functional departments. They should be advised to prepare the drafts within a specific timeframe.

Step 8. Document Control

Once the necessary quality management system documentation has been generated, a documented system must be created to control it. Control is simply a means of managing the creation, approval, distribution, revision, storage, and disposal of the various types of documentation. Document control systems should be as simple and as easy to operate as possible, sufficient to meet ISO 9001:2000 requirements and that is all.

Document control should include:

- Approval for adequacy by authorized person before issue
- Review, updating and re-approval of documents by authorized person(s)
- Identification of changes and of the revision status of documents
- Availability of relevant versions of documents at points of use
- Identification and control of documents of external origin
- Assurance of legibility and identifiable nature of documents
- Prevention of unintended use of obsolete documents.

The principle of ISO 9000 document control is that employees should have access to the documentation and records necessary to fulfil their responsibilities.

Step 9. Implementation

It is good practice to implement the QMS being documented as the documentation is developed, although this may be more effective in larger firms. In smaller companies, the QMS is often implemented simultaneously throughout the organization. Where phased implementation takes place, the effectiveness of the system in selected areas can be evaluated. It would be a good idea initially to evaluate areas where the chances of a positive evaluation are high, to maintain the confidence of both management and staff in the merits of implementing the QMS. The implementation progress should be monitored to ensure that it is effective and conforms to the standard. These activities include internal quality audit, formal corrective action and management review.

Step 10. Internal Quality Audit

As the system is being installed, its effectiveness should be checked by regular internal quality audits, conducted to verify that the installed QMS:

- conforms to the planned arrangements, to the requirements of the standard (ISO 9001:2000) and to the QMS requirements established by the organization

- is effectively implemented and maintained.

Even after the system stabilizes and starts functioning, internal audits should be planned and performed as part of an ongoing strategy. A few staff members should be trained to carry out internal auditing. Use ISO 19011 for guidance in auditing, auditor qualification and programmes.

Step 11. Management Review

When the installed quality management system has been operating for three to six months, an internal audit and management review should be conducted and corrective actions implemented. The management reviews are conducted to ensure the continuing suitability, adequacy and effectiveness of the quality management system. The review should include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

The input to management review should include information on:

- results of audits
- customer feedback
- process performance and product conformity
- status of preventive and corrective actions
- follow-up actions from previous management reviews
- changes that could affect the quality management system
- recommendations for improvements.

Management reviews should also address the pitfalls to effective implementation, including lack of CEO commitment, failure to involve everyone in the process, and failure to monitor progress and enforce deadlines.

Step 12. Pre-assessment Audit

When system deficiencies are no longer visible, it is normally time to apply for certification. However, before doing so, a pre-assessment audit should be arranged with an independent and qualified auditor. Sometimes certification bodies provide this service for a nominal charge. The pre-assessment audit would provide a degree of confidence for formally going ahead with an application for certification.

Step 13. Certification and Registration

Once the QMS has been in operation for a few months and has been stabilized, a formal application for certification could be made to a selected certification agency. The certification agency first carries out an audit of the documents (referred to as an "adequacy audit"). If the documents conform to the requirements of the quality standard, then on-site audit is carried out. If the certification body finds the system to be working satisfactorily, it awards the organization a certificate, generally for a period of three years. During this three-year period, it will carry out periodic surveillance audits to ensure that the system is continuing to operate satisfactorily.

Step 14. Continual Improvement

Certification to ISO 9001 should not be an end in itself, but rather one should continually seek to improve the effectiveness and suitability of the quality management system through the use of:

- quality policy
- quality objectives
- audit results
- analysis of data
- corrective and preventive actions
- management review.

Although implementing a QMS can be costly, many companies have implemented ISO 9001:2008 and have obtained improved results. One of the key reasons for this is that many companies overlook the complexity of the implementation processes and the organizational changes that are needed to ensure the QMS is fully functional. A fully functional QMS leads to increased customer satisfaction and continuous improvement of business results. The existence of documentation is a key requirement of a functional QMS in a company. Despite the positive questionnaire results the implementation of ISO 9001:2008 is highly recommended for continuous improvement.

5.5 FUTURE RESEARCH DIRECTIONS

Future research regarding the following can be beneficial for ISO 9008:2001:

- Since the deployment of ISO 9001:2008 in South Africa is still fairly recent, additional research is required to validate the proposed implementation strategy and roadmap, thus future research will need to be performed to ensure the successful implementation of ISO 9001:2008.
- Identifying the gap between the practices and the major factors causing the gap.
- Culture and change management in implementing ISO 9008:2001, and this can be an additional research to determine how it has been successfully applied by different companies.

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Dear Respondent

This is a research Questionnaire on: "Topic" A critical evaluation of the quality management system at the medical company in the North West.

Your response to the questionnaire will assist in ascertaining whether the quality management system at the company is effective and efficient.

Your cooperation in completing the attached questionnaire will be highly appreciated. All responses will be STRICTLY CONFIDENTIAL. Results will be presented as a summary of all respondents.

Should there be any queries, concerns or suggestions regarding this study, please contact the researcher.

Thank you

Maki Nonyane (Mrs)

072 125 8030

SECTION A:

BIOGRAPHICAL DATA

KINDLY COMPLETE THE FOLLOWING SECTION BY TICKING OFF THE APPROPRIATE BOXES:

1. Age?

20 – 30	1
31 – 40	2
41 – 50	3
50+	4

2. Gender?

Female	1
Male	2

3. Occupation?

Accountant	1
Registered Nurse	2
Nurse	3
Administration Officer	4
Electrician	5
Radiographer	6
Driver	7
Other (Specify):	8

4. Level?

Manager	1
Matron	2
Supervisor	3
Other (Specify).....	4

5. Department?

Casualty	1
ICU	2
Theatre	3
X Ray	4
Finance	5
Maintenance	6
Other (Specify).....	7

SECTION B:

Quality perceptions

This section measures your perception of quality. Please mark with a cross (x) in the applicable box to rate your level of agreement or disagreement. **Please mark one box only.**

Quality Management System (QMS) Practices

NO	ITEM	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE
1	Management takes action to continually improve process performance.				
2	The process for designing and building is clear.				
3	The company's quality functions play a key role.				
4	The company and its suppliers are mutually beneficial.				
5	The company enhances the ability of both to create value.				
6	There is a continuous evaluation of various business strategies at the company.				

Quality Management System (QMS) Effectiveness

NO	ITEM	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE
1	Top management is committed to development and implementation of QMS.				
2	The company documents its quality policy.				
3	The company's objectives are clear and documented.				
4	All documents in QMS are legible.				
5	All documents in QMS are identified.				
6	All documents in QMS are reviewed.				
7	All documents in QMS are authorised up to date.				
8	Records are kept to demonstrate how QMS is operating.				
9	QMS practices at the company are effective.				
10	The company has a formal system of reporting.				
11	Activities and related resources are managed as a process.				
12	Employees at a company work as a team.				
13	The company determines the work environment needed to achieve conformity to product requirement.				

14	The company manages the work environment needed to achieve conformity to product requirement.				
15	Management at the company ensures that responsibilities are defined and communicated.				
16	Employees are satisfied with the working condition				

Factors affecting QMS

Leadership

NO	ITEM	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE
1	Management at the company establishes unity of purpose of the organisation.				
2	Management at the company establishes direction of the organisation				
3	Management conducts reviews and ensure available resources				
4	Employee participation is decisive in inspiring action on quality management.				

SECTION C: Job satisfaction

This section measures your feelings towards your work related to needs. Please mark with a cross (x) in the applicable box to rate your level of agreement or disagreement. Please mark one box only.

NO	ITEM	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE
1	Management is committed to employee education and training				
2	The company determines the necessary competence for personnel performing work affecting conformity to product requirement.				
3	The company maintains appropriate records of training, skills and experience.				
4	I meet the minimum experience, and qualification.				
5	I meet the minimum statutory requirements.				
6	HR issues have an effect on quality service.				
7	HR issues have an effect on turnaround time.				

Employee morale

NO	ITEM	STRONGLY AGREE	AGREE	DISAGREE	STRONGLY DISAGREE
1	I participate in operating decisions such as (Planning, goal setting and monitoring of performance).				
2	Top management encourages me to achieve quality				
3	I am dedicated to my job.				
4	I am dedicated to the improvement of myself.				
5	I am well rewarded for my superior performance.				

Thank You Very Much